



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

April 10, 1990

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP)
Regulations

GLP Regulation Advisory No. 11

FROM: David L. Dull, Director
Laboratory Data Integrity Assurance Division

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Policy & Grants Division of the Office of Compliance Monitoring. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please contact Francisca Liem at FTS 475-9864.

Attachment

cc: C. Musgrove



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MEMORANDUM

Dear

This is in response to your letter of February 26, 1990, to Steve Howie of my staff. In that letter, you requested guidance regarding EPA Interpretation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs) In regard to field residue studies. Specifically, you asked If weather data and soil analyses required GLP compliance when used to support GLP studies, and what statement of compliance would be required when State, Federal, or Independent laboratories are used for residue studies.

Any study performed in support of a FIFRA research or marketing permit must be In accordance with applicable GLP standards. If soil analyses or weather measurements are made as part of such a study, they must comply with the GLPs. In the case that non-study information Is referenced, e.g., local weather data, the data generation need not be under GLPs as long as it Is clear that a reference to such data Is being made. Finally, the statement of compliance or noncompliance Is necessary regardless of the affiliation(s) of testing laboratories employed in the study.

If you have any questions concerning this response, please contact Steve Howie of my staff at (202) 475-7786.

Sincerely yours,
/s/ John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

cc: David Dull
GLP File